Detailed Action

This Office Action is in response to the Applicant's reply received 4/08/2010. Claims 23-39 are pending. Claims 24-29, 34-36, 38 and 39 are withdrawn. Claims 1-22 are cancelled. No Claims have been amended. No Claims are new. Claims 23, 30-33 and 37 are considered in this Office Action.

Objection to the Claims

Claim 39 is misnumbered as claim 49. For the purposes of examination it will be referred to in this action as 39 but appropriate correction is required.

Response to Restriction/Election

Applicant's response to the species election without traverse filed on 4/08/10 by FAX is acknowledged. In a phone call to the Examiner that same day the Applicant elected Category (3) of part (b) of the requirement for PCT Rule 13.2. This includes the product (the glucose fructose biopolymer of claim 23), the process specially adapted to make this product (claims 30-33) and the first appearing use for this product (claim 37).

As stated in the telephone conversation part (a) referring to PCT Rule 13.1 was entered into the action by mistake and should be disregarded and only part (b) was relevant for this restriction requirement.

Therefore claims 24-29, 34-36, 38 and 39 are withdrawn as being directed towards non-elected groups or multiple methods of use that will not be considered at this time.

Claim Rejections - 35 USC § 101 and 112 First Paragraph

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 37 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either an asserted utility or a well established utility.

The claim reads as a "use" or process claim but does not set forth any steps to execute, make or use the invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 37 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Simply amending claim 37 to read as a composition where the fructose glucose biopolymer is included will remove both of these rejections from claim 37 only.

Also the claimed invention is directed to non-statutory subject matter. Claims 23, 30-33 and 37 appear to be directed towards a product of nature since it is not clear if the biopolymer obtained from *L. lactis* NRRLB-30656 is in some way isolated ***and*** purified. The term "obtained" is broad and not clear how the hand of man was used to ensure that this composition is a "nonnaturally occurring manufacture of composition of

matter" (MPEP 2105). Simply including the terms "an isolated and purified" biopolymer will remove this rejection.

Claim Rejections - 35 USC § 112 For Biological Deposit

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23, 30-33 and 37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ a specific strain of *Lactococcus lactis* NRRLB-30656. It is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.

It appears that a deposit was made in this application as filed as noted on page 4 of the substitute specification. However, it is not clear if the deposit meets all of the criteria set forth in 37 CFR 1.801-1.809. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner.

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.

2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.

3. States that the deposited material has been accorded a specific (recited) accession number.

4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.

6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.

7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

Claim Rejections - 35 USC § 112 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23, 30-33 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear which of the products of *L. lactis* NRRLB-30656 are being claimed in 23. The claim reads on limitations for a) a glucose and fructose biopolymer b) metabolism products comprising an enzymatic extract and c) metabolism products comprising a preparation having two types of glucosyltransferase and fructosyltransferase activity. Each of products a)-c) have unique and distinct properties and it is unclear which to search or how the limitations of one affect the other. Also it is unclear if the glucose and fructose monomers of the biopolymer are exclusive or inclusive. In other words, it is unclear to the Examiner if the biopolymer is "consisting of glucose and fructose" monomers or is "comprising glucose and fructose" monomers.

In the interest of compact prosecution only limitations directly pertaining to the biopolymer will be given significant patentable weight. The other limitations will be considered Product-by-Process limitations used to make the biopolymer. As a reminder, M.P.E.P. § 2113 state "Product by process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps". Therefore the product being examined in the claims includes the biopolymer and not the steps or materials (such as the *L. lactis* bacteria) used to obtain this composition.

This distinction is important in the method claims of 30-33 since this method and indeed even the claims do not directly limit that the enzymatic extract or preparation

must come from *L. lactis* NRRLB-30656. Therefore any enzymatic extract or preparation such as a micro-organism will read on these claims. This is especially true since the method steps include "fermentation" which is a process that requires at the very least biological cells and not enzymes *in-vitro*.

Claim 33 is indefinite because of the limitation that the "cellulose membrane having a pore size greater than 10,000-30,000 Dalton". The unit Dalton is for molecular weight and is not a geometrical unit to define a pore size. Therefore it is unclear how the pore sizes are limited. This claim also contains a range within a range of "a pore size greater than 10,000-30,000 Dalton" is indefinite since it is unclear if the pores size is greater than 10,000 Dalton or greater than 30,000 Dalton. Indeed this is unclear since a pore size of, for example, 15,000 Daltons would read on the first range but not on the second. It appears the Applicant wishes to claim a molecular weight cutoff similar to those seen in a dialysis filtration. It may be helpful to advance prosecution to amend the claim with this type of limitation.

Claims 23, 30-33 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 23 the two following limitations do not have support in the as filed specification:

- The biopolymer having a composition of 0.2 to 0.7 glucose/fructose ratio
- Non-hygroscopic.

The specification does not appear to have any expressly stated support for "0.2 to 0.7 glucose/fructose ratio" in the clean copy of the substitute specification filed 2/13/09. Indeed the specification does not appear to have any information as to the specific glucose/fructose composition in the Also the term "non-hygroscopic" was not found in the specification. Furthermore the specification clearly states that the biopolymer is "slightly hygroscopic" (specification page 21, "Humidity adsorption") which seems to contradict the limitation in the claim.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 or 103 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Or in the alternative

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 23, 30, 33, and 37 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Manaca De Nadra et al. (Int. J. of Food Microbiology, 1995).

This claim is drawn to a glucose and fructose biopolymer having the following properties:

a) 0.2 to 0.7 glucose/fructose ratio;

b) 900-1,100 kDa molecular weight;

c) Two vitreous transition points, one between 20 °C and 30 °C and another between 190 °C and 220 °C;

d) Stability in aqueous solutions with a pH value from 2-9;

e) 1,000 to 3,000 centipoise viscosity when the biopolymer is at 10% to 20% concentration in an aqueous solution at 30 °C;

f) Non-hygroscopic; and

g) Highly soluble in water, able to form a hydrogel homogeneous dispersions at maximum concentration of 50% w/v.

The Applicant is reminded that the source of this biopolymer, *L. lactis* NRRLB-30656 is a product-by-process limitation and that is not provided significant patentable weight for a composition. MPEP 2113 is clear that the "patentability of a product does not depend on its method of production".

Manaca De Nadra et al. teach a biopolymer that has a glucose/fructose ratio calculated between 0.2 and 0.7 (Table 1, Glucose value divided by Fructose value) as a viscous agent in wine (pg 105). The log value of the molecular weight of their

biopolymer is 6 (Fig 1, insert graph). This corresponds to a molecular weight of 1000 kDa. This biopolymer is water soluble (pg 105, last full paragraph) and stable in aqueous solutions at pH of 7 (pg 103, Section 2.5).

Manaca De Nadra et al. is silent as to characteristics c, e, f and g. However these are inherent characteristics of the structure of the polymer and are determined by experimentation. The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not Applicants' biopolymer differs, and if so to what extent, from the biopolymer discussed in Manaca de Nardra et al. The prior art biopolymer has the same structural limitations of glucose/fructose ratio, molecular weight and pH stability as the claimed biopolymer. The cited art taken as a whole demonstrates a reasonable probability that the biopolymer of the prior art is either identical or sufficiently similar to the claimed biopolymer and that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

Merely because a characteristic of a prior art biopolymer is not disclosed in a reference does not make that biopolymer patentable. Applicants' biopolymer possesses inherent characteristics which might not be displayed in the tests used in Manaca de Nardra et al. Clear evidence that the biopolymer of the cited prior art does not possess a critical characteristic that is possessed by the claimed biopolymer (for example, a structural comparison or side-by-side comparison of characteristics c, e, f, and g) would advance prosecution and might permit allowance of claims to Applicants' biopolymer.

Manaca de Nardra et al. isolates their biopolymer using the following steps (pg 102, Section 2, Materials and Methods):

1) A preparation *Pediococcus pentosaceus* is fermented in MRS medium that comprising a sucrose (5 g/L) at pH ranging from 4.5 to 6.5 for 22 hours so the enzymes can produce the biopolymer;

2) The cells are centrifuged and removed from the supernanent;

3) The biopolymer is precipitated with three voluemes of absolute ethanol;

4) This biopolymer precipitate was centrifuged again and the supernanten removed;

5) The biopolymer precipitate was dried at 37 ^{o}C;

6) The biopolymer was redissoved in distilled water to obtain a stock solution;

7) The biopolymer was further purified by either paper chromatography or ultrafiltration on a Sepharose column.

Therefore claims 23, 30, 33, and 37 are either anticipated or obvious in view of the above references.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 23, 30-33, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manaca de Nardra et al. as applied to 23, 30, 33, and 37 above and for the following rational.

The description and rejection of claims 23, 30, 33, and 37 was previously presented above in the 35 USC 102/103 rejection.

While the reference listed above does not specifically teach the limitations of claims 31 and 32 concerning the reaction concentrations, temperatures and humidity used to dry or lyophilize the biopolymer, nor the exact volumes of 96% ethanol to precipitate the biopolymer, nor the specific sequence of precipitation of claim 32 one of ordinary skill in the art would recognize these limitations are result effective variables that determine the recover yield, experimental time and storage of the biopolymer. Absent any teaching of criticality by the applicant concerning these limitations, it would be *prima facie* obvious that one of ordinary skill in the art would recognize these limitations are result effective variables which can be met as a matter of routine optimization (M.P.E.P. § 2144.05 II). Furthermore it would be obvious to one of ordinary skill in the art to repeat and rearrange steps of precipitation, dissolution and drying to improve yield and purity.

Therefore claims 23, 30-33, and 37 are obvious in view of the above reference.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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